

1. (Original) A drug product comprising:
a drug formulation comprising a mixture of at least a drug and a hydrofluoroalkane propellant;
a pressurized container filled with said drug formulation; and,
a pouch constructed from materials comprising one or more metallic foil layers and one or more moisture absorbing materials.
2. (Original) The drug product of claim 1 wherein the drug is selected from the group consisting of (-)-4-amino-3,5-dichloro- α -{[6-{2-(2-pyridinyl)ethoxy}hexyl]-amino}methyl}benzenemethanol, flunisolide, tiredane, triamcinalone, isoprenaline, metaproterenol, perbuterol, peproterol, rimeterol, ephedrine, fenoterol, formoterol, atropine, oxitropium, acetonide, phenylephrine, phenylpropanolamine, terbutaline, isoetharine, tulobuterol, orciprenaline, salts, esters and solvates thereof, and combinations thereof.
3. (Currently Amended) The drug product of claim 1 wherein the drug is a member selected from the group consisting of fluticasone, beclomethasone, salmeterol, albuterol, budesonide, ~~salbutamol~~, ipratropium, salts, esters and solvates thereof, and combinations thereof.
4. (Original) The drug product of claim 1 wherein the drug is fluticasone propionate.
5. (Original) The drug product of claim 1 wherein the drug is beclomethasone dipropionate.
6. (Original) The drug product of claim 1 wherein the drug is salmeterol xinafoate.
7. (Original) The drug product of claim 1 wherein the drug is a salt, solvate or ester a combination of salmeterol and ipratropium.
8. (Original) The drug product of claim 1 wherein the drug is salmeterol xinafoate and ipratropium bromide.

9. (Original) The drug product of claim 1 wherein the drug is a salt, solvate or ester of a combination of salmeterol and fluticasone.

10. (Original) The drug product of claim 9 wherein the drug is a combination of salmeterol xinafoate and fluticasone propionate.

11. (Currently Amended) The drug product of claim 1 wherein the drug is ~~salbutamol~~ albuterol sulphate.

12. (Original) The drug product of claim 1 wherein the hydrofluoroalkane propellant is a member selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoro-n-propane and mixtures thereof.

13. (Original) The drug product of claim 1 wherein the hydrofluoroalkane propellant is 1,1,1,2-tetrafluoroethane.

14. (Original) The drug product of claim 1 further including a metering valve engaged to the pressurized container.

15. (Original) The drug product of claim 14 further including an actuator adapted to engage the metering valve and the pressurized container.

16. (Original) The drug product of claim 15 wherein the moisture absorbing material is a desiccant.

17. (Original) The drug product of claim 16 wherein the actuator, metering valve and pressurized container and metering valve are contained within the pouch.

18. (Original) The drug product of claim 16 wherein the desiccant is selected from the group consisting of nylon, silica gel, alumina, bauxite, anhydrous, calcium sulfate, water-absorbing clay, activated bentonite clay, a molecular sieve zeolite and combinations thereof.

19. (Original) The drug product of claim 1 wherein the drug formulation consists essentially of a drug and a hydrofluoroalkane propellant.
20. (Original) The drug product of claim 15 wherein desiccant is in the form of a coating, lining, film or mesh.
21. (Original) The drug product of claim 20 wherein the desiccant is a nylon.
22. (Original) The drug product of claim 1 wherein the metallic foil layer is aluminum.
23. (Original) The drug product of claim 22 wherein the aluminum foil layer has a thickness in the range of 9-25 μm .
24. (Original) The drug product of claim 23 wherein the aluminum foil layer has a thickness of about 12.7 μm .
25. (Original) The drug product of claim 1 wherein the drug formulation consists essentially of a drug and a hydrofluoroalkane propellant.
26. (Original) The drug product of claim 1 wherein the pouch is vacuum sealed.
27. (Original) The drug product of claim 1 wherein the pouch is purged with nitrogen gas.
28. (Original) The drug product of claim 1 further comprising a second desiccant loosely contained within the pouch.
29. (Original) The drug product of claim 1 further comprising a second desiccant contained within the pressurized container.
30. (Original) The drug product of claim 1 wherein the metallic foil layer has a thickness in the range of 1-100 μm .

31. (Original) The drug product of claim 1 wherein the metallic foil layer has a thickness in the range of 3-70 μ .

32. (Original) The drug product of claim 1 wherein the metallic foil layer has a thickness in the range of 5-50 μ .

33. (Original) The drug product of claim 1 wherein the metallic foil layer has a thickness in the range of 6-20 μ .

34. (Original) The drug product of claim 1 wherein the metallic foil layer has a thickness of about 9 μ .

35. (Original) The drug product of claim 1 wherein the pouch includes one or more protective layers.

36. (Original) The drug product of claim 35 wherein the protective layer has a thickness in the range of 1-40 μ .

37. (Original) The drug product of claim 35 wherein the protective layer has a thickness in the range of 4-30 μ .

38. (Original) The drug product of claim 35 wherein the protective layer has a thickness in the range of 10-23 μ .

39. (Original) The drug product of claim 35 wherein the protective layer has a thickness of about 12 μ .

40. (Original) The drug product of claim 1 wherein the metallic foil layer includes a metal collected from the group consisting of aluminum, tin, iron, zinc and magnesium.

41. (Original) The drug product of claim 40 wherein the metallic foil layer includes aluminum.

42. (Original) The drug product of claim 40 wherein the metallic foil layer of the pouch is constructed by the act of vacuum deposition.

Applicant Docket No.: PG 4113 USW
U.S. Serial No. 09/971,799
Page 6 of 15

43. (Original) The drug product of claim 40 wherein the metallic foil layer of the pouch is constructed by the act of sputtering.

44. (Original) The drug product of claim 1 wherein the drug formulation further includes an excipient.

45. (Original) The drug product of claim 44 comprising 0.01-5% w/w of the excipient.

46. (Original) The drug product of claim 44 comprising 0.05-5% w/w of the excipient.

47. (Original) The drug product of claim 44 comprising 0.1-5% w/w of the excipient.

48. (Original) The drug product of claim 44 comprising 0.1-1% w/w of the excipient.

49. (Original) The drug product of claim 44 wherein the excipient is a member selected from the group consisting of one or more surfactants, preservatives, flavorings, antioxidants, anti-aggregating agents, co-solvents, and combinations thereof.

50. (Original) The drug product of claim 49 wherein the co-solvent is ethanol or diethyl ether.

51. (Original) The drug product of claim 49 wherein the co-solvent is C₂₋₈ aliphatic alcohols or C₂₋₆ aliphatic polyols.

52. (Original) The drug product of claim 49 wherein the co-solvent is glycerol, isopropanol or propylene glycol.

53. (Original) The drug product of claim 35 wherein the pouch further includes one or more heat seal layers.

64. (Original) The drug product of claim 35 wherein the pouch further includes one or more adhesive layers.

55. (Original) The drug product of claim 35 wherein the protective layer includes one or more desiccants impregnated therein.

56. (Original) The drug product of claim 53 wherein one or more heat seal layers include one or more desiccants impregnated therein.

57. (Original) The drug product of claim 54 wherein one or more adhesive layers include one or more desiccants.

58. (Original) The drug product of claim 35 wherein the protective layer includes a polyester.

59. (Original) The drug product of claim 58 wherein the protective layer has a thickness of about 12 μ .

60. (Original) The drug product of claim 22 wherein the metallic foil layer has a thickness of 9 μ .

61. (Original) The drug product of claim 53 wherein the heat seal layer includes a member selected from the group consisting of an ionomer, a polyolefin, a cyclopolyolefin copolymer and combinations thereof.

62. (Original) The drug product of claim 61 wherein the heat seal layer includes an ionomer selected from the group consisting of crosslinked ethylene-methacrylic acid and ethylene acrylic acid copolymer, and wherein the heat seal layer has a thickness of 50 μ .

63. (Original) The drug product of claim 53 wherein the heat seal layer has a thickness in the range of 1-100 μ .

64. (Original) The drug product of claim 53 wherein the heat seal layer has a thickness in the range of 5-70 μ .

65. (Original) The drug product of claim 53 wherein the heat seal layer has a thickness in the range of 10-60 μ .

66. (Original) The drug product of claim 53 wherein the heat seal layer has a thickness in the range of 20-55 μ .

67. (Original) The drug product of claim 53 wherein the heat seal layer has a thickness of 50 μ .

68. (Original) The drug product of claim 53 wherein the heat seal layer is adhesively laminated to the metallic foil layer by an adhesive layer.

69. (Original) The drug product of claim 35 wherein the protective layer is adhesively laminated to the metallic foil layer.

70. (Original) The drug product of claim 20 wherein desiccant is adhesively laminated to one or more of the protective layer, the metallic foil layer or the heat seal layer.

71. (Original) A drug product comprising:
a drug formulation comprising a mixture of at least a drug and a hydrofluoroalkane propellant;
a pressurized means for containing said drug formulation; and,
a means for pouching the pressurized means constructed from materials comprising one or more metallic foil layers and one or more moisture absorbing materials.

72. (Original) A drug product comprising:
a container containing a pressurized drug formulation comprising a propellant and a drug dispersed and/or dissolved in said propellant; and
an overwrap constructed from a moisture impermeable, flexible material enclosing said container.

73. (Original) The drug product of claim 72, further comprising a desiccant located within said overwrap.

74. (Original) The drug product of claim 73, wherein said desiccant is selected from the group consisting of a molecular sieve zeolite, alumina, silica gel, bauxite, anhydrous calcium sulphate, water-absorbing clay, activated bentonite clay, and combinations thereof.

75. (Original) The drug product of claim 73, wherein the desiccant is contained within a sachet.

76. (Original) The drug product of claim 75, wherein the desiccant is silica gel.

77. (Original) The drug product of claim 76, comprising in the range of 1 to 10 grams silica gel.

78. (Original) The drug product of claim 72, further comprising a desiccant placed loosely in the container or as part of an assembly attached to the container.

79. (Original) The drug product of claim 72 wherein the propellant is selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoro-n-propane, and combinations thereof.

80. (Original) The drug product of claim 79 wherein the propellant is 1,1,1,2-tetrafluoroethane.

81. (Original) The drug product of claim 72 wherein the drug is albuterol sulfate.

82. (Original) The drug product of claim 72 wherein the drug is fluticasone propionate.

83. (Original) The drug product of claim 72 wherein the drug is salmeterol xinafoate.

84. (Original) The drug product of claim 72 wherein the drug is a combination of fluticasone propionate and salmeterol xinafoate.

85. (Original) The drug product of claim 72 wherein the drug is beclomethasone dipropionate.

86. (Original) The drug product of claim 72 wherein the drug is a combination of a salt, ester or solvate thereof of salmeterol and ipratropium.

87. (Original) The drug product of claim 86 wherein the drug is a combination of a combination of salmeterol xinafoate and ipratropium bromide.

88. (Original) The drug product of claim 72 wherein the drug is selected from the group consisting of (-)-4-amino-3,5-dichloro-alpha-(((6-(2-(2-pyridinyl)ethoxy)hexyl)-amino)methyl)benzenemethanol, flunisolide, tiredane, triamcinalone, isoprenaline, metaproterenol, perbuterol, pepraterol, rimiterol, ephedrine, fenoterol, formoterol, atropine, oxitropium, acetonide, phenylephrine, phenylpropanolamine, terbutaline, isoetharine, tulobuterol, orciprenaline, salts, esters and solvates thereof, and combinations thereof.

89. (Currently Amended) The drug product of claim 72 wherein the drug is a member selected from the group consisting of fluticasone, beclomethasone, salmeterol, albuterol, budesonide, ~~salbutamol~~, ipratropium, salts, esters and solvates thereof, and combinations thereof.

90. (Original) The drug product of claim 72 further including a metering valve engaged to the container.

91. (Original) The drug product of claim 90 further including an actuator adapted to engage the metering valve and the container.

92. (Original) The drug product of claim 91 wherein the actuator, metering valve and container and metering valve are contained within the overwrap.

93. (Original) The drug product of claim 72 wherein the drug formulation consists essentially of a drug and a hydrofluoroalkane propellant.

94. (Original) The drug product of claim 72 wherein the overwrap is vacuum sealed.

95. (Original) The drug product of claim 94 wherein the overwrap is purged with nitrogen gas.

96. (Original) The drug product of claim 72 wherein the drug formulation further includes an excipient.

97. (Original) The drug product of claim 96 comprising 0.01-5% w/w of the excipient.

98. (Original) The drug product of claim 96 comprising 0.05-5% w/w of the excipient.

99. (Original) The drug product of claim 96 comprising 0.1-5% w/w of the excipient.

100. (Original) The drug product of claim 96 comprising 0.1-1% w/w of the excipient.

101. (Original) The drug product of claim 96 wherein the excipient is a member selected from the group consisting of one or more surfactants, preservatives, flavorings, antioxidants, anti-aggregating agents, co-solvents, and combinations thereof.

102. (Original) The drug product of claim 101 wherein the co-solvent is ethanol or diethyl ether.

103. (Original) The drug product of claim 101 wherein the co-solvent is C₂₋₆ aliphatic alcohols or C₂₋₆ aliphatic polyols.

104. (Original) The drug product of claim 101 wherein the co-solvent is glycerol, isopropanol or propylene glycol.

105. (Original) A drug product comprising:
a means for containing a pressurized drug formulation comprising a propellant and a drug dispersed and/or dissolved in said propellant; and
a moisture impermeable, flexible means for enclosing said container.

106. (Original) A drug product comprising:
an aerosol dispenser for dispensing metered amounts of fluid material from a reservoir, the dispenser comprising a container defining a reservoir, and a dispensing valve;

a drug formulation located within said aerosol dispenser comprising a pharmaceutically acceptable medicament and propellant; and

a flexible package overwrapping and sealing said aerosol dispenser, wherein said flexible package is impermeable to water vapor and permeable to said propellant,

and wherein said flexible package substantially prevents ingress of water vapor and particulate matter into said enclosed volume and permits egression of said propellant.

107. (Original) The drug product of claim 106 further comprising a brochure disclosing product information.

108. (Original) The drug product of claim 106 further comprising a container for enclosing said flexible package.

109. (Original) The drug product of claim 106 further comprising a sachet containing a desiccant located within the flexible package.

110. (Original) The drug product of claim 109 wherein the desiccant is silica gel.

111. (Original) The drug product of claim 110 comprising in the range of 1 to 10 grams silica gel.

112. (Original) The drug product of claim 109 wherein the desiccant is a member selected from the group consisting of a molecular sieve zeolite, alumina,

silica gel, bauxite, anhydrous calcium sulphate, water-absorbing clay, activated bentonite clay, and combinations thereof.

113. (Original) The drug product of claim 106 wherein the drug formulation consists essentially of the medicament and a hydrofluoroalkane alkane.

114. (Original) The drug product of claim 106 wherein the propellant is selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoro-n-propane, and combinations thereof.

115. (Original) The drug product of claim 106 wherein the propellant is 1,1,1,2-tetrafluoroethane.

116. (Original) The drug product of claim 106 wherein the medicament is albuterol sulfate.

117. (Original) The drug product of claim 106 wherein the medicament is fluticasone propionate.

118. (Original) The drug product of claim 106 wherein the medicament is salmeterol xinafoate.

119. (Original) The drug product of claim 106 wherein the medicament is a combination of fluticasone propionate and salmeterol xinafoate.

120. (Original) The drug product of claim 106 wherein the medicament is beclomethasone dipropionate.

121. (Original) The drug product of claim 106 wherein the medicament is a combination of a salt, ester or solvate thereof of salmeterol and ipratropium.

122. (Original) The drug product of claim 121 wherein the medicament is a combination of a combination of salmeterol xinafoate and ipratropium bromide.

123. (Original) The drug product of claim 106 wherein the medicament is selected from the group consisting of (-)-4-amino-3,5-dichloro-alpha-{{6-(2-(2-